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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,861	07/18/2003	Richard Leske	1760-289	9984

32905 7590 10/13/2004
JONDLE & ASSOCIATES P.C.
9085 EAST MINERAL CIRCLE
SUITE 200
CENTENNIAL, CO 80112

EXAMINER

ROBINSON, KEITH O NEAL

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 10/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/622,861	LESKE ET AL.	
	Examiner	Art Unit	
	Keith O. Robinson, Ph.D.	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 18 July 2003.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-20 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) Claim(s) _____ is/are allowed.
6) Claim(s) 1-20 is/are rejected.
7) Claim(s) 1,2,7,12 and 14 is/are objected to.
8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date *May 19, 2004*.

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.

5) Notice of Informal Patent Application (PTO-152)
6) Other: _____.

DETAILED ACTION

Claim Objections

Claims 1, 2, 7, 12, and 14 are objected to for its inclusion of blanks (____). It is assumed that the blanks will be replaced by an ATCC Accession Number.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are drawn to cotton seed 00X01BR, methods of using said cotton seed, and parts thereof.

Since the seed is essential to the claimed inventions, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the plant is not so obtainable or available, the requirements of 35 U.S.C. 112 may be satisfied by a deposit of the plant. The specification does not disclose a repeatable process to obtain the plant and it is not apparent if the plant is readily available to the public. Thus, a deposit is required for enablement purposes. A deposit of 2500 seed of each of the claimed embodiments is considered sufficient to ensure public availability. It is noted that Applicants have deposited the seed of this invention

(see page 31 of the specification), but there is no indication in the specification as to the access of this invention afforded to the Commissioner upon request, the removal of all restrictions upon availability to the public, the duration that the deposit will be maintained, or the viability of the biological material at the time of deposit. If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. 1.801-1.809, Applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that

- (a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;
- (d) a test of the viability of the biological material at the time of deposit (see 37 C.F.R. 1.807) and,

(e) the deposit will be replaced if it should ever become inviable.

Claims 7, 9-11, 13-15, and 18-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Claim 7 is broadly drawn to a cotton plant regenerated from the tissue culture of regenerable cells of cotton variety 00X01BR wherein said plant is “capable of” expressing the morphological characteristics of 00X01BR. Since it is unclear whether plant actually expresses these characteristics, the claim encompasses tissue-culture-derived somaclonal variants of cotton variety 00X01BR, with mutations at one or more loci, which would not possess all the morphological and physiological traits that are inherent in cotton variety 00X01BR. The specification, however, does not give a written description of such a regenerated plant as to its genetic, morphological, and/or physiological characteristics.

Claims 9-11 and 13 are broadly drawn to a hybrid cotton seed produced by crossing cotton variety 00X01BR with another cotton plant and the seed and plants derived from such a cross. Claims 9 and 10 are broadly drawn to any hybrid cotton seed or plant, respectively, produced from such a cross. Claim 11 is drawn to an F2 plant with, at most, 25% of its genome being derived from cotton cultivar 00X01BR. The claims seem to infer any cotton plant will be crossed with cotton variety 00X01BR. The specification does not give a written description as to the genetic, morphological, and/or physiological composition of the claimed cotton plants or

their non-00X01BR parents. Furthermore, the specification fails to give any description as to the genetic composition of cotton variety 00X01BR and that of its parents. Since all cotton plants will vary in their genetic, morphological, and physiological composition, the genetic, morphological, and physiological background of the hybrid seeds or plants derived from such a cross have not been adequately characterized.

Claim 13 is broadly drawn to any cotton plant, or parts thereof produced by crossing cotton variety 00X01BR with another cotton plant. The specification does not give a written description as to the genetic, morphological, or physiological composition of the cotton plant or its non-00X01BR parent. Since all cotton plants will vary in their genetic, morphological, and physiological composition, the genetic, morphological, and physiological background of the hybrid seeds or plants derived from such a cross have not been adequately characterized.

Claims 14-15 are broadly drawn to a method for producing a cotton variety 00X01BR-derived cotton plant by crossing 00X01BR with a second cotton plant, growing the seed from said cross, crossing the 00X01BR-derived cotton plant with itself, growing the seed from said cross, and repeating the crossing and growing steps from 0-7 times to generate further cotton variety 00X01BR-derived cotton plants. The claims seem to infer the use of any cotton plant as the second cotton plant. The specification does not give a written description as to the genetic, morphological, and/or physiological composition of the second cotton plant. Since all cotton plants will vary in their genetic, morphological, and physiological composition, the genetic, morphological, and physiological background of the hybrid seeds or plants derived from such a cross have not been adequately characterized.

Furthermore, in step (e) of claim 14 it states that the crossing and growing steps are to be repeated “0 to 7 times to generate further cotton variety 00X01BR-derived cotton plants”. The claim seems to infer that all plants from the cross will be harvested. Selfing a plant 0 to 7 times will give a different frequency of homozygous versus heterozygous plants with each selfing generation, with some plants having the genotype of the second cotton plant that was used in the cross. With each selfing generation heterozygosity decreases and homozygosity increases, so the seed produced from an F1 plant that is derived from the cross in claim 14 would display plants that exhibit 25% homozygous 00X01BR genotypes, 50% heterozygous genotypes, and 25% homozygous “second plant” genotypes when using a single gene model. In contrast, after four generations of selfing, the same seed produced from an F1 plant that is derived from the cross in claim 14 would display plants that exhibit 47% homozygous 00X01BR genotypes, 6% heterozygous genotypes, and 47% homozygous “second plant” genotypes when using a single gene model. Therefore, almost half of the harvested plants will possess the genotype of the “second plant” based on the interpretation of claim 14 and would not be a cotton variety 00X01BR-derived cotton plant. Though selection in a breeding program at the fourth or greater generation is well known in the art, there is no written description in the specification as to which trait or traits (phenotypic or genetic) are being selected for that would make a cotton variety 00X01BR-derived cotton plant or even if these traits are dominant or recessive. Furthermore, there is no guidance as to the role epistasis or linkage drag may play in such a cross. Each generation of selfing will result in further rearrangements of dominant and recessive alleles at each locus. Thus each generation will comprise a multitude of individuals with different traits

and different collections of traits, and no written description has been provided in the specification for these unknown plants of unknown genetic or morphological composition.

Claims 18-20 are broadly drawn to a method for producing a cotton plant that contains in its genetic material a transgene by crossing the cotton plant variety 00X01BR with a cotton plant of any genotype that has only been characterized as containing a transgene and the cotton plants or parts thereof. Claim 18 seems to infer the crossing of cotton plant variety 00X01BR with any cotton plant that contains any transgene, but the specification does not provide a written description of the genetic or morphological identity of the other cotton plant nor does it describe what type of transgene the other cotton plant is in possession of, with regard to sequence or encoded function. Furthermore, there is no written description that provide evidence of such plants having been created by the method, as is claimed in claim 20.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention “requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials”. University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that “naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not description of that material”. Id. Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to “visualize or recognize the identity of the members of the genus”. Id.

See MPEP Section 2163, page 156 of Chapter 2100 of the August 2001 version, column 2, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

Given the failure of the specification to describe the claimed plant, methods of using it are also inadequately described. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention. See the written description guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 4, 2001/ Notices: pp. 1099-1111.

Claims 7, 9-11, 13-15, and 18-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 7 is broadly drawn to a cotton plant regenerated from the tissue culture of regenerable cells of cotton variety 00X01BR wherein said plant is “capable of” expressing the morphological characteristics of 00X01BR. Since it is unclear whether plant actually expresses these characteristics, the claim encompasses tissue-culture-derived somaclonal variants of cotton

variety 00X01BR, with mutations at one or more loci, which would not possess all the morphological and physiological traits that are inherent in cotton variety 00X01BR. The specification, however, does not give a written description of such a regenerated plant as to its genetic, morphological, and/or physiological characteristics, therefore, one skilled in the art would not know how to use the claimed plant.

Claims 9-11 and 13 are broadly drawn to a hybrid cotton seed produced by crossing cotton variety 00X01BR with another cotton plant and the seed and plants derived from such a cross. Claims 9 and 10 are broadly drawn to any hybrid cotton seed or plant, respectively, produced from such a cross. Claim 11 is drawn to an F2 plant with, at most, 25% of its genome being derived from cotton cultivar 00X01BR. The claims seem to infer any cotton plant will be crossed with cotton variety 00X01BR. The specification does not give any guidance as to the genetic, morphological, and/or physiological composition of the claimed cotton plants or their non-00X01BR parents. Furthermore, the specification fails to give any guidance as to the genetic composition of cotton variety 00X01BR and that of its parents. Since all cotton plants will vary in their genetic, morphological, and physiological composition, it would be unpredictable as to the genetic, morphological, and physiological background of the hybrid seeds or plants derived from such a cross. Thus one skilled in the art would not know how to use the plants or seeds.

Claim 13 is broadly drawn to any cotton plant, or parts thereof produced by crossing cotton variety 00X01BR with another cotton plant. The specification does not give any guidance as to the genetic, morphological, or physiological composition of the second cotton plant. Since all cotton plants produced by this method will vary in their genetic, morphological, and

physiological composition, it would be unpredictable as to the genetic, morphological, and physiological background of the hybrid seeds or plants derived from such a cross.

Claims 14-15 are broadly drawn to a method for producing a cotton variety 00X01BR-derived cotton plant by crossing 00X01BR with a second cotton plant, growing the seed from said cross, crossing the 00X01BR-derived cotton plant with itself, growing the seed from said cross, and repeating the crossing and growing steps from 0-7 times to generate further cotton variety 00X01BR-derived cotton plants. The claims seem to infer the use of any cotton plant as the second cotton plant. The specification does not give any guidance as to the genetic, morphological, and/or physiological composition of the second cotton plant. Since all cotton plants will vary in their genetic, morphological, and physiological composition, it would be unpredictable as to the genetic, morphological, and physiological background of the hybrid seeds or plants derived from such a cross. Thus one skilled in the art would not know how to use said seeds or plants.

Furthermore, in step (e) of claim 14 it states that the crossing and growing steps are to be repeated “0 to 7 times to generate further cotton variety 00X01BR-derived cotton plants”. The claim seems to infer that all plants from the cross will be harvested. Selfing a plant 0 to 7 times will give a different frequency of homozygous versus heterozygous plants with each selfing generation, with some plants having the genotype of the second cotton plant that was used in the cross. With each selfing generation heterozygosity decreases and homozygosity increases, so the seed produced from an F1 plant that is derived from the cross in claim 14 would display plants that exhibit 25% homozygous 00X01BR genotypes, 50% heterozygous genotypes, and 25% homozygous “second plant” genotypes when using a single gene model. In contrast, after four

generations of selfing, the same seed produced from an F1 plant that is derived from the cross in claim 14 would display plants that exhibit 47% homozygous 00X01BR genotypes, 6% heterozygous genotypes, and 47% homozygous “second plant” genotypes when using a single gene model. Therefore, almost half of the harvested plants will possess the genotype of the “second plant” based on the interpretation of claim 14 and would not be a cotton variety 00X01BR-derived cotton plant. Though selection in a breeding program at the fourth or greater generation is well known in the art, there is no guidance in the specification as to which trait or traits (phenotypic or genetic) are being selected for that would make a cotton variety 00X01BR-derived cotton plant or even if these traits are dominant or recessive. Furthermore, there is no guidance as to the role epistasis or linkage drag may play in such a cross. Each generation of selfing will result in further rearrangements of dominant and recessive alleles at each locus. Thus each generation will comprise a multitude of individuals with different traits and different collections of traits, and no guidance has been provided in the specification for these unknown plants of unknown genetic or morphological composition.

Claims 18-20 are broadly drawn to a method for producing a cotton plant that contains in its genetic material a transgene by crossing the cotton plant variety 00X01BR with a cotton plant of any genotype that has only been characterized as containing a transgene and the cotton plants or parts thereof. Claim 18 seems to infer the crossing of cotton plant variety 00X01BR with any cotton plant that contains any transgene, but the specification does not provide any guidance as to the genetic or morphological identity of the other cotton plant, or which or what type of transgene the other cotton plant is in possession of, nor does it provide any of such plants having

been created by the method, as is claimed in claim 20. Thus one skilled in the art would not know how to make or use such a plant.

The state of the art teaches that it is unpredictable whether a gene or genes for conferring a phenotype in one plant genetic background may be transferred into the genetic background of another plant to confer the phenotype in said different plant. For example, Hunsperger et al (US Patent No. 5,523,520) disclosed a specific gene trait in the genetic background of one plant which has been introgressed into the genetic background of another plant of the same species, that did not result in the expected transfer gene trait (see, column 3, lines 26-46). Kraft et al (Theoretical and Applied Genetics 101:323-326, 2000) teach that linkage disequilibrium effects and linkage drag prevent the making of plants comprising a single transferred trait and that effects are unpredictably genotype specific and loci dependent in nature. Kraft et al teach that linkage disequilibrium is created in breeding materials when several lines become fixed for a given set of alleles at a number of different loci, and that very little is known about the plant breeding material, and therefore, is an unpredictable effect in plant breeding (see, page 323, column 1, lines 7-15). Eshed et al (Genetics 143:1807-1817, 1996) teach that epistatic genetic interactions from the various genetic components comprising contributions from different genomes may affect quantitative traits in a genetically complex and less than additive fashion (see, pages 1815-1816). Finally, in a study of cotton, Mishra et al (Plant Cell Tissue and Organ Culture 73: 21-35, 2003) teach that linkage drag is a concern during introgression of transgenes into elite cultivars (see page 22, second column, lines 6-13 and page 34, second column, lines 21-25). Sakhanokho et al (Crop Sci. 41 : 1235-1240, 2001) teach that the regeneration of commercial cotton varieties through transgenic methods has not been successful and that those

plants that have been successfully regenerated are agronomically poor (see page 1235, first column, first paragraph).

Neither the instant specification nor the prior art provides evidence that such linkage disequilibrium, linkage drag, or epistatic effects are not common in cotton breeding materials, such that one or more genes can be transferred from one genetic background to another, wherein the resultant cotton progeny would either express the desired trait or maintain all of the other desirable 00X01BR genes and traits.

Given the lack of guidance in Applicant's specification regarding a multitude of non-exemplified hybrids, somaclonal variants, single gene conversions, the unpredictability of transferring said genes, and the breadth of the claims, one skilled in the art would not be able to make and/or use the inventions claimed without undue experimentations.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7, 16, and 19 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

In claim 7, "is capable of expressing" does not clearly recite whether or not the characteristics are actually expressed. Replacement of "is capable of expressing" with "has" or "expresses" would overcome the rejection.

In claims 16 and 19, “transgene is selected from the group consisting of: herbicide resistance, insect resistance, and disease resistance” is confusing because a transgene confers a trait but is not equal to that trait. Replacement of “is” before “selected” with “confers a trait” would overcome the rejection.

Claim 16 is further indefinite in its recitation of “the cotton plant, or parts thereof, of claim 2, wherein the plant or parts thereof [has] been transformed”. It is confusing to simultaneously characterize the non-transformed plant of claim 2 as being transformed. Submission of a process claim reciting a process of transforming the cotton plant of claim 2 with a transgene conferring herbicide, insect, or disease resistance, followed by a product-by-process claim drawn to a transformed cotton plant produced by that method would overcome the rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 15 is rejected under 35 U.S.C. 102(b) as being anticipated by Gutierrez et al (Crop Sci. 42: 1841-1847, 2002). The claim reads on a method of producing any cotton plant or parts thereof with repeated crossing and growing steps from 0 to 7 times. The claimed method of making the plant would not confer a unique property to the resultant non-00X01BR cotton plant.

Gutierrez et al teach making of cotton plants with repeated crossing and growing steps (see page 1842, first column, second full paragraph).

The cotton plant taught by the prior art differs from the claimed cotton plant only in their method of making, namely by the use of backcrossing in the prior art. However, the method of making the claimed cotton plant would not distinguish it from the prior art cotton plant. See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejectable over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products. See *In re Best*, 195 USPQ 430, 433 (CCPA 1997), which teaches that where the prior art product seems to be identical to the claimed product, except that the prior art is silent as to a particularly claimed characteristic or property, then the burden shifts to Applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention.

Claims 1-14 and 16-20 are deemed free of the prior art, given the failure of the prior art to teach or suggest an exemplified cotton variety which possesses a unique genetic complement and unique collection of traits as that of cotton variety 00X01BR.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith O. Robinson, Ph.D. whose telephone number is 571-272-2918. The examiner can normally be reached on Monday - Friday 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, Ph.D. can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

October 8, 2004

KOR

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180-1638

